

AUG 28 2007

Commissioner for Patents United States Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

Office of Regulatory Policy **HFD - 7** 5600 Fishers Lane (Rockwall II Rm. 1101) Rockville, MD 20857

Attention: Beverly Friedman

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 6,395,716. The application was filed on December 21, 2006, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term extension. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (571)272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till

Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

cc:

James Dean Johnson, Ph.D. KING & SPALDING, LLP 1180 Peachtree Street, 34th Floor Atlanta, Ga 30309

RE: TYZEKA® (telbivudine) FDA Docket No. 2007E-